



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,749	02/25/2005	Kenji Kouchi	T3736-9374US01	2075
62574	7590	09/28/2007		
SHERIDAN ROSS P C SUITE 1200 1560 BROADWAY DENVER, CO 80202			EXAMINER SKOWRONEK, KARLHEINZ R	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,749	Applicant(s) KOUCHI ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-21 are pending.

Claims 1-21 are being examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09 January 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Specification

The use of the trademark MICROSOFT WINDOWS has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is unclear regarding the phrase "when subsequent biological information of the determined abnormal biological information is not determined as the abnormal biological information" as recited on lines 2-4. The phrase and claim do not provide the metes and bounds of action that is taken upon satisfying the condition of the phrase as recited on lines 2-4.

Claim 7 is also unclear because the phrase "when subsequent biological information of the determined abnormal biological information is not determined as the abnormal biological information" appear to be contradictory. It is unclear how subsequent data that has been determined to be abnormal is determined to be different data. For the purpose of examination the claim as a whole will be interpreted to mean that the data has two different formats indicating abnormality over time and normality over time.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 16 is drawn to a biological information trend displayed object. The object of claim 16 does not fall into the statutory classes of invention because a displayed object is non-functional descriptive material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1631

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3-4, 6, 10, and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ascher et al. (US PAT 4,809,705).

The claims are drawn to a device having means for obtaining information, making a determination of abnormal information, and displaying information. In some embodiments, the display is modified with a visual alarm and thereby altering the display style. In some embodiments, the biological information is displayed in association with the source of biological information. In some embodiments, the device makes a determination of if the information exceeds or falls below a threshold.

Ascher et al. shows a device for obtaining biological information that is specifically an electrocardiogram. The device is microprocessor controlled (col. 1, line 65). Ascher et al. shows that the device comprises a display means (col. 1, line 63). Ascher et al. shows the display means displays a time-series by showing an electrocardiogram (col. 3, line 15-23). Ascher et al. shows the device also comprises a determining means (col. 3, line 4-11). Ascher et al show that the determining means as a means for determining abnormal data as exemplified by determining if heart beat rate crosses predetermined upper and lower thresholds and sounding an alarm (col. 3, line 25-28). Ascher et al. shows the display is modified with a visual alarm and thereby altering the display style (col. 3, line 24-28). Ascher et al. shows the device has a means for obtaining biological information through leads that are attached to a patient (col. 2, line 25-47). Ascher et al. shows an embodiment in which the biological

information is displayed in association with the source of biological information (figure 3 and col. 3, line 19-23). Ascher et al. shows in an embodiment that the device makes a determination of if the information exceeds or falls below a threshold (col. 3, line 26-28).

Claims 1-3, 10-11, 14-15, and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Newlan et al. (18th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Amsterdam, 5.4.1 : ECG, ST-segment and Ischemia, p. 1355-1356, 1996).

The claims are drawn to a device having means for obtaining information, making a determination of abnormal information, and displaying information. In some embodiments, the device is encoded on a computer readable medium. In some embodiments, multiple information sources can be displayed. In some embodiments, multiple information is in the same style. In some embodiments, information shows different behaviors. In some embodiments, display means presents information related to ST level trends and source related lead information

Newlan et al. shows a trend display system and device for obtaining biological information determining and displaying information related to cardiac function. The device comprises a storage review unit having a display means, a means for determining abnormal data, and means for obtaining biological information (p1355, col. 2, para. 2). Newlan et al shows an abnormal information determining means to provide clinical alarms upon abnormal information as a result from for example measurement lead failure (p. 1355, col. 2, para 3). Newlan et al. shows a computer readable medium

(p. 1355, col. 1, para 3). Newlan et al. shows that the multiple information sources can be displayed (p. 1356, col. 1, para 6). Newlan et al. shows that multiple information is in the same style (p. 1356, col. 1, para 6). Newlan et al. shows that information shows different behaviors (p. 1356, col. 1, para 6). Newlan et al. shows display means presents information related to ST level trends and source related lead information (p. 1355, col. 2, para. 3 and p. 1356, col. 2, para. 2-3).

Claims 1, 3-5, 7, 8, 10-13, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dia medical system Kabushiki Kaisha "JP787" (Japanese patent JP 51-787, cited on IDS 1/9/06).

The claims are drawn to a device having means for obtaining information, making a determination of abnormal information, and displaying information. In some embodiments, the determination of an abnormal event causes the display to present the information. In some embodiments, the trend style change corresponds to a change in color of the trend information. In some embodiments, the color-coded source undergoes a color change when the source exceeds or drops below a threshold. In some embodiments, the display means allows to discriminate between cases where current information is abnormal; past and current information are abnormal and past information is abnormal but current information is not abnormal.

JP787 shows a trend display device for biological information. JP787 shows the device has an information obtaining means, a abnormal information determination means, and a display means (p. 1). JP787 shows that the display mean displays

Art Unit: 1631

information determined to be abnormal and identifies its source (p. 6, para 2). JP787 shows the determination of an abnormal event causes the display to present the information (p. 6, para 2). JP787 shows the trend style change corresponds to a change in color of the trend information (p. 5-6). JP787 shows that each source of information is coded by color (p. 5). JP787 shows the color coded source undergoes a color change when the source exceeds or drops below a threshold (p. 5 and exemplified on p. 6). JP787 shows that the display means allows to discriminate between cases where current information is abnormal; past and current information are abnormal and past information is abnormal but current information is not abnormal (p.7-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1631

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dia medical system Kabushiki Kaisha "JP787" (Japanese patent JP 51-787, cited on IDS) as applied to claims 1, 3-5, 7, 8, 10-12, and 17-20 above, in view of van Weele et al. (US PAT 5,631,825).

Claim 9 is directed to the design of visual alerts areas distinct from the trend lines displayed by the display means.

JP787 shows the information is highlighted by color change to alert a user to an abnormal condition as described above.

JP787 does not teach display areas with inner and outer indication areas.

van Weele et al. shows the uses of color-coded icons to indicate monitored events (col. 1, line 55-61). van Weele et al. shows that the advantage of color coding and icon usage is more effective supervision of processes (col. 1, line 65-67).

It would have been obvious to modify the trend display device of JP787 with the use of color-coded icons of van Weele et al. because van Weele et al. shows that the advantage of color coding and icon usage is more effective supervision of processes. The display areas of claim 9 are viewed as obvious to the color-coded icons of van

Weele et al. and represent an aesthetic design change. In re Seid , 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

20 September 2007

/KRS/

Karlheinz R. Skowronek
Assistant Examiner, Art Unit 1631

J.S. Brusca 21 September 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER